DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 23, 2014

Covidien
Mr. Jim Welsh
Vice President, Regulatory Affairs
15 Hampshire Street
Mansfield, MA 02048

Re: K141479
Trade/Device Name: Kangaroo™ Enteral Feeding Sets with ENFit connectors
Regulation Number: 21 CFR 880.5725
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: LZH
Dated: November 20, 2014
Received: November 21, 2014

Dear Mr. Welsh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141479

Device Name

Kangaroo™ Enteral Feeding Sets with ENFit small bore connectors

Indications for Use *(Describe)*
The Kangaroo™ Enteral Feeding Set with ENFit connectors delivers nutritional formula to the gastrointestinal system of a patient age Infant and older who is physically unable to eat and swallow. Not for use with neonates. The feeding sets are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary
Kangaroo Enteral Feeding Set with ENFit connectors

In accordance with section 513(i) of the SMDA and as defined in 21CFR Part 807.92 this summary is submitted by:

Covidien
15 Hampshire Street
Mansfield, MA 02048
Date Prepared: December 23, 2014

a. Contact Person

Jim Welsh
VP, Regulatory Affairs
Covidien
Telephone: (508) 261-8532
Fax: (508) 261-8461

b. Name of Medical Device

Common Name: tube, feeding

U.S. FDA Classification Product Code: LZH

U.S. Regulation Description: Infusion Pump, 21 CFR 880.5725

Proprietary / Trade Name: Kangaroo™ Enteral Feeding Set with ENFit connectors

c. Identification of Legally Marketed Device(s)

Covidien Kangaroo™ ePump Enteral Feeding Pump and Enteral Feeding Set, K040196

d. Device comparison summary

The table below provides a comparison of the key attributes of the predicate and proposed devices.

Device Comparison Summary		
	Predicate Device	Proposed Device
Device Name	Kangaroo™ e-pump	Kangaroo™ Enteral Feeding Set with ENFit connectors
Device Description	Enteral feeding pump and disposable enteral feeding sets	Enteral Feeding sets for use with Kangaroo Feeding pumps
Intended Use	Intended for use in patients with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding, pump and pump set. The pump and feeding sets are intended to be used in alternate, acute and home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition at a controlled rate to a patients gastrointestinal system.	Intended for use in patients age Infant and older with any condition requiring enteral feeding and/or enteral hydration, which can be accomplished by means of an enteral feeding, pump and pump set. Not for use with neonates. The feeding sets are intended to be used in clinical or home care settings by users ranging from laypersons to clinicians. The purpose of this device is to deliver enteral nutrition to a patient's gastrointestinal system.
Sterility	Includes sterile and non-sterile feeding sets	Non-sterile
Technological Characteristics	The feeding sets are based on peristaltic pumping using a rotating wheel which presses against the tubing and moves the fluid at a controlled rate. The connection to the patient enteral access device is a stepped connector.	The feeding sets are based on peristaltic pumping using a rotating wheel which presses against the tubing and moves the fluid at a controlled rate. The connection to the patient enteral access device is an ENFit Connector compliant to ISO 80369-3
Design	The pump set incorporates 5 basic segments: • Fluid reservoir(s), which may be an attached bag (500ml or 1000ml) or a spike for connection to a formula container • Tubing from fluid reservoir to pump (24 inch)	The pump set incorporates 5 basic segments: • Fluid reservoir(s), which may be an attached bag (500ml or 1000ml) or a spike for connection to a formula container • Tubing from fluid reservoir to pump (9 or 24 inch)

	• Pump interface module (peristaltic tubing) • Tubing from pump to patient connector (66 inches) • Patient connector (stepped connector)	• Pump interface module (peristaltic tubing) • Tubing from pump to patient connector (66 inches) Patient connector (ENFit connector compliant to ISO 80369-3)
Materials/Chemical composition	Polyvinyl chloride (PVC) • Feeding bags and caps • Tubing • Patient connector Silicone • Peristaltic tubing Polycarbonate • Valve body HDPE • Valve stem LDPE • Dust Cover ABS • Spike Strontium Ferrite / nylon • Set ID magnets	Polyvinyl chloride (PVC) • Feeding bags and caps • Tubing • Drip Chamber Silicone • Peristaltic tubing Polycarbonate • Valve body HDPE • Valve stem • Feeding container LDPE • Dust Cover • Hanger strap ABS • Spike Strontium Ferrite / nylon • Set ID magnets Copolyester • ENFit connector PE/EVA/EPE • Spike seal washer Polystyrene • Roller clamp

e. Discussion of technological differences

The Kangaroo™ Enteral Feeding Set with ENFit connectors are intended for use with existing feeding pumps, and as such the technological differences are limited to the incorporation of the new ENFit connector which is compliant to ISO 80369-3. This connector is part of an industry wide effort to address misconnections by adopting a uniform connector that has been engineered to meet the objective of IS0 80369-1, small-bore connectors for liquids and gases in healthcare applications - part 1: general requirements

f. Discussion of Nonclinical testing

- Biocompatibility testing in accordance with ISO 10993-1:2009, Biological Evaluation of medical Devices- Part 1: Evaluation and Testing has demonstrated the biological safety of parts of the medical device which may indirectly contact the patient, and is consistent with FDA "Draft Guidance for Industry and FDA staff, Use of international Standard ISO 10993 'Biological Evaluation of medical Devices Part 1: Evaluation and Testing,'" issued on April 23, 2013. Similar testing had been conducted for the predicate device.

- Stability testing of the proposed device evaluated the key performance properties of the feeding set after accelerated aging in support of the expiration date which will be applied to the device.

- Usability and human factors testing was conducted as part of the design of the ENFit connector.

g. Clinical testing

Clinical evaluations were not relied upon for evidence of safety of effectiveness, or for a determination of substantial equivalence.

h. Conclusions

This information provided within this pre-market notification demonstrates that the Kangaroo™ Enteral Feeding Set with ENFit connectors is as safe, as effective, and performs as well as or better than the legally marketed device, therefore I find the subject device to be substantially equivalent to the predicate device. The addition of the ENFit connector, which is compliant with ISO 80369-3 is intended to improve device performance by addressing the risk of misconnections.

End of Summary